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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,610	08/22/2003	Lola M. Reid	320727.00123	8277
27160	7590	07/11/2005		
KATTEN MUCHIN ROSENMAN LLP 525 WEST MONROE STREET CHICAGO, IL 60661-3693			EXAMINER WOITACH, JOSEPH T	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/645,610

Applicant(s)

REID ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10, 21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This application filed August 22, 2003, is a continuation of 09/534,487, filed March 24, 2000, which is a continuation of 09/115,920, filed July 15, 1998, now US Patent 6,146,889, which is a continuation of 08/751,546, filed November 18, 1996, now US Patent 5,789,246, which is a divisional of 08/265,696, filed June 24, 1994, now abandoned, which is a continuation of 07/741,128, filed August 7 1991, now abandoned.

Applicants' amendment filed April 11, 2005, has been received and entered. The specification has been amended. Claims 11-20 have been cancelled. Claims 21 and 22 have been added. Claims 1-10, 21 and 22 are pending.

### ***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on October 28, 2004 was acknowledged. Non-elected claims 11-20 have been cancelled. No new arguments have been provided (see Applicants amendment, page 5). Newly added claims 21 and 22 are drawn to the elected invention.

The requirement is still deemed proper and Final.

Claims 1-10, 21, 22 are pending. Claims 1-10, 21 and 22 drawn to a liver precursor cell capable of differentiating into biliary cells, are currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required.

The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Applicants note that the amended address information has been provided on an application data sheet and that this information will be relied upon over the information in the declaration, pointing to the MPEP in support of there statements. Applicants request that in the interest of time that the ADS be considered over providing a new declaration. See Applicants amendment page 6.

Examiner acknowledges that the MPEP provides guidance on interpreting the information provided on the declaration and/or application data sheet, however has not found the guidance that allows this to overcome requirements of 37 CFR 1.52, in particular non-initialed amendments. While the address information for Andreas Ochs may be current as set forth in the application data sheet, this does not overcome the defect of a non-initialed amendment to the declaration.

***Specification***

The disclosure objected to because the priority data presented in the first line of the specification appears to be incorrect, in particular the listing of 08/256,696 as a priority document is withdrawn.

The amendment to the specification has addressed the basis of the objection.

***Priority***

Applicant has complied with the conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120.

The amendment to the specification to correct the priority claim has addressed the issues raised concerning the he priority claim.

***Claim Objections***

Claim 7 stands objected to because of the following informalities: The use of the trademark Millicell has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

It is noted that the term has been capitalized to indicate that it is a trademark name, however it is not presented with generic terminology.

Appropriate correction is required.

Claims 2-9 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn.

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The amendment to claim 2 to note characteristics of the cell culture versus the inherent properties of the cell has obviated the basis of the objection.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn.

The amendment to claim 1 to recite an "isolated" composition addresses the basis of the rejection.

***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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Claims 1, 2, 3, 4, 8-10 stand rejected and newly added claims 21 and 22 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3-7 of prior U.S. Patent No. 5,789,246. This is a double patenting rejection.

Claims 1, 6, 7 stand rejected and newly added claims 21 and 22 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 2, 3 of 6,146,889. Claims 1 are duplicates of each other. Claims 6, 7, recite further limitations to claim 1 of the present application and are exact duplicates of claims 2 and 3.

Applicants note the present claims indicate that composition comprises cells that are capable of differentiating into **biliary** cells while the cited patents recite the capability of differentiating into **hepatocytes**. See Applicants' amendment, page 8. Applicants arguments have been fully considered, but not found persuasive.

As noted previously, the claims of the present application, which is dependent on claim 1, are exactly the same in wording and scope as claims of cited patents. For example, claims 1 and 2 recite all the limitations present in claim 1 of the patent. The difference in the recitation of the cell be capable of differentiating into **biliary** cells and the capability of differentiating into **hepatocytes** recited in the cited patents is noted, however upon review of the specification it appears that this is the same stem cell with both capabilities. In this case, the instant claims reciting that the cell has the capability to differentiate into a biliary cell is an inherent property of the cell in the composition claims in the cited patents, and does not further limit the scope of the claims. Examiner can not find support in the specification that the specification that two different cells are present or even the methodology that would produce the claimed composition wherein it would contain one cell with the capable of differentiating into **biliary** cells while not also containing/producing a cell capability of differentiating into **hepatocyte** cells. While the terms recited in the claims appear to be directed to a different scope in the description and characterization of the cells in the composition, the claims appear to be completely the same in

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breadth because it is simply a further characterization of the stem cell, and the specification only provides at best a composition with cells have the claimed capability.

For the reasons above and of record, the rejection is maintained.

### ***Obvious Type Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 10-22 of U.S. Patent No. 6,146,889 is withdrawn.

Claims 1-10 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,576,207 is withdrawn.

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Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of U.S. Patent No. 5,789,246 is withdrawn.

The terminal disclaimers filed April 11, 2005 have been received and entered. The disclaimer over each of the issued patents have been accepted, and obviate the basis of the rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-9 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendment to claim 2 to indicate properties of the cell culture and not the capabilities of the cell has addressed the basis of the rejection.

Newly amended claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 7 has been amended to recite a trademark product, however a trademark name is subject to change. The metes and bounds of the claim are indefinite because the use of trademark product is relative to the companies use of the name is and is subject to change, and fails to sufficiently set forth in generic terminology what is encompassed by the claim.

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Deleting the trademark term would obviate the basis of the rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10 rejected under 35 U.S.C. 102(e) as being anticipated by Kuri-Harcuch *et al.*

(US Patent 5,030,105-IDS reference) is withdrawn.

Claims 1-10 rejected under 35 U.S.C. 102(b) as being anticipated by Tsai *et al.* ( Biol. Abstr. 22434-IDS reference) is withdrawn.

Applicants' arguments and amendments to the claims have been fully considered and found persuasive. Specifically, the products as claimed are differentiated from those presented in both Kuri-Harcuch *et al.* and Tsai *et al.*

***Conclusion***

No claim is allowed.

Claim 5 is objected to because it is dependent on a rejected claim.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

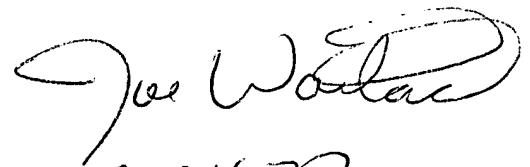
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach



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